510(k) Summary

NAME OF SPONSOR:

Ortho Development Corporation
12187 South Business Park Drive
Draper, Utah 84020

510(k) CONTACT:

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Regulatory Affairs Manager
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OCT 11 2013

DATE PREPARED:

April 24, 2013

PROPRIETARY NAME:

Balanced Knee® System High Flex Vitamin E PS Tibial Insert and Patella

COMMON NAME:

Total Knee Replacement Prosthesis

CLASSIFICATION:

21 CFR 888.3560, Knee joint, patellofemorotibial, polymer/metal/polymer semi-constrained cemented prosthesis, Class II device

DEVICE PRODUCT CODE:

OIY, JWH

PREDICATE DEVICES:

Balanced Knee® System (K994370), *Ortho Development Corp.*

Balanced Knee® System High Flex PS (K123457), *Ortho Development Corp.*

Highly Cross-Linked Vitamin E UHMWPE Tibial Insert (K091956), *DJO Surgical/Encore Medical*

Device Description

The Balanced Knee® System High Flex Vitamin E (High Flex Vit E) PS tibial insert and patella are machined from extensively crosslinked, compression molded, Vitamin E UHMWPE. Both components are single use only. The High Flex Vit E PS tibial insert must be used in conjunction with the High Flex PS femoral component (K123457). Used together, these components are designed to accommodate increased range of motion up to 150° of flexion. The High Flex Vit E patella may be used in conjunction with the Balanced Knee® System (BKS) femoral components (K994370), the BKS modular femoral components (K060569), or the High Flex PS femoral components (K123457). Both the High Flex Vit E PS tibial insert and patella may be used in conjunction with the BKS standard and modular tibial trays, tibial augments, and stems to complete the semi-constrained modular knee prosthesis. The tibial trays, tibial augments, and stems were approved under K994370 and K031201.

Intended Use

The Balanced Knee® System High Flex Vitamin E PS tibial insert and patella are intended for use in cemented total knee arthroplasty procedures with the following indications:

1. Loss of knee joint configuration and joint function.
2. Osteoarthritis of the knee joint.
3. Rheumatoid arthritis of the knee joint.
4. Post-traumatic arthritis of the knee joint.
5. Valgus, varus, or flexion deformities of the knee joint.
6. Revision procedures where other treatments or devices have failed.

Technological Characteristics

Feature	Equivalent Device
Indications for Use and Design	Ortho Development: Balanced Knee® System (K994370) Ortho Development: Balanced Knee® System High Flex PS (K123457)
Material: Extensively Crosslinked Vitamin E Polyethylene UHMWPE (α-tocopherol)	DJO Surgical/Encore Medical: Vit E UHMWPE Tibial Insert (K091956)

There is only one difference between the High Flex Vit E PS insert when compared to the BKS High Flex PS insert: the implementation of a different material, crosslinked Vitamin E UHMWPE. Likewise, the High Flex Vit E patella is identical to the BKS patella except for the crosslinked Vitamin E UHMWPE material. The indications for use for the High Flex Vit E PS tibial insert and patella are identical to the indications for use for the BKS High Flex. The crosslinked Vitamin E UHMWPE for the High Flex Vit E PS insert and patella undergoes substantially equivalent fabrication and final processing as its predicate, DJO/Encore's Vitamin E UHMWPE tibial insert.

Performance Data

The following non-clinical testing was performed to determined substantial equivalence to the predicate devices:

Property	Result
Range of Motion	Up to 150° flexion; Substantially Equivalent to predicate device, BKS High Flex
Femorotibial Constraint	Substantially Equivalent to predicate device, BKS High Flex
Femorotibial Contact Area	Substantially Equivalent to predicate device, BKS High Flex
Patellofemoral Constraint	Substantially Equivalent to predicate device, BKS High Flex
Patellofemoral Contact Area	Substantially Equivalent to predicate device, BKS High Flex
PS Spine Fatigue	Substantially Equivalent
Insert Assembly/ Disassembly	Substantially Equivalent
Crosslinking Characterization of High Flex Vit E	Substantially equivalent or better than BKS
Vitamin E Characterization of High Flex Vit E	Substantially equivalent or better than BKS
High Flex Knee Wear	Decrease in wear over BKS

Basis for Substantial Equivalence

Ortho Development believes that the High Flex Vit E PS tibial insert and patella are substantially equivalent to the previously cleared predicate devices based on similarities in intended use, design, materials, manufacturing methods, packaging, and mechanical performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

October 11, 2013

Ortho Development Corporation
Mr. Tom Haueter
Regulatory Affairs Manager
12187 South Business Park Drive
Draper, Utah 84020

Re: K131337
Trade/Device Name: Balanced Knee® System High Flex Vitamin E PS Tibial Insert and Patella
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH, OIY
Dated: September 6, 2013
Received: September 9, 2013

Dear Mr. Haueter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use Form
Ortho Development
Balanced Knee® System High Flex Vitamin E PS Tibial Insert and Patella 510(k)

510(k) Number (if known): _K131337_____

Device Name: Balanced Knee® System High Flex Vitamin E PS Tibial Insert and Patella

Indications for Use:

The Balanced Knee® System High Flex Vitamin E PS tibial insert and patella are intended for use in cemented total knee arthroplasty procedures with the following indications:

1. Loss of knee joint configuration and joint function.
2. Osteoarthritis of the knee joint.
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6. Revision procedures where other treatments or devices have failed.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Casey L. Hanley, Ph.D.

Division of Orthopedic Devices